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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,767	12/18/2006	Rajendra Narayanrao Kankan	PAC/22106 US (4137-01000)	1294
30652	7590	06/12/2008	EXAMINER	
CONLEY ROSE, P.C. 5601 GRANITE PARKWAY, SUITE 750 PLANO, TX 75024			DAVIS, BRIAN J	
			ART UNIT	PAPER NUMBER
			1621	
			MAIL DATE	DELIVERY MODE
			06/12/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/596,767	KANKAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brian J. Davis	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15-23, 26, 27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-23, 26 and 27 is/are allowed.
- 6) ☒ Claim(s) 1-12 and 29 is/are rejected.
- 7) ☒ Claim(s) 3, 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/18/06</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Claim Objections***

Claims 3 and 12 are objected to because of the following informalities: the claims do not terminate with a period (after the structure). Claims must begin with a capital letter and end with a period. MPEP 608.01(m). Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 1621

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 325571 A1 (CAPLUS abstract; patent family of US 5,382,600 cited in the IDS).

Applicant claims racemic tolterodine free crystalline base and its pharmaceutical composition.

EP 325571 A1 teaches racemic tolterodine free base (RN=124936-74-9) and its pharmaceutical composition.

Applicant principally distinguishes over the prior art in that the crystalline form and a particular purity is claimed. However, to be patentable, a novel form of an old compound must possess a new utility or a utility of a different type. A mere improvement in properties does not render a novel form of an old compound patentable. *In re Weijland*, 587 OG 3, 33 CCPA 837, 154 F.2d 133; 1946 CD 175, 69 USPQ 86; *Ex parte Hald*, Paper 15 in US 2,647,145.

Claims 2 and 3 are included in this rejection because, there are a number of decisions holding that where the purification of an old product results in a mere change in degree in its properties, the purified form is unpatentable. *Ex parte Windhaus*, 15 USPQ 45 (POBA 1931); *In re Ridgeway*, 76 F.2d 602, 25 USPQ 202 (CCPA 1935); *In re Mertz*, 97 F.2d 599, 38 USPQ 143 (CCPA 1938); *In re Macallum*, 102 F.2d 614, 41

Art Unit: 1621

USPQ 146 (CCPA 1939); *In re King*, 107 F.2d 614, 43 USPQ 400 (CCPA 1939); *Ex parte Sparhawk*, 64 USPQ 339 (POBA 1945); *In re Weijlard*, 154 F.2d 133, 69 USPQ 86 (CCPA 1946); *In re Johnson*, 94 F.2d 978, 37 USPQ 75 (CCPA 1938); *Ex parte Cavillito*, 89 USPQ 449 (POBA 1950); *Ex parte Snell*, 86 USPQ 496 (POBA 1950); *In re Fisher*, 307, F.2d 948, 135 USPQ 22 (CCPA 1962); *Ex parte Hartop*, 139 USPQ 525 (POBA 1962); *Ex parte Siddiqui*, 156 USPQ 426 (POBA 1966); *Ex parte Schmidt-Kastner*, 153 USPQ 473 (POBA 1963).

Claims 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over CN1364757 (CAPLUS and CASREACT abstracts).

Applicant claims a process for producing tolterodine (claim 4). The dependent claims further defined the process.

CN1364757 teaches applicant's general process where a compound of formula (II) is deprotected using pyridine hydrochloride at 210°C.

Applicant principally distinguishes over the prior art in that miscellaneous reaction parameters are slightly altered (temperature profiles), or explicitly specified, (solvent) and that a product of a particular purity is produced. However, these limitations are mere engineering expediciencies and one of ordinary skill in the art - without undue experimentation and in the absence of unexpected results - would have found it obvious to choose reaction parameters such that the reaction ran as desired.

***Allowable Subject Matter***

Claims 15-23, 26 and 27 are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached at 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/596,767  
Art Unit: 1621

Page 6

/Brian J. Davis/  
Primary Examiner, Art Unit 1621  
6/8/08